UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**

PLAINTIFFS' REPLY IN SUPPORT OF *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF PUNAM KELLER, PH.D.

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I. INTRODUCTION

Defendants fail to meaningfully address Plaintiffs' arguments in favor of excluding Dr. Keller. Instead, Defendants double down on Dr. Keller's highly speculative and uninformed "*maybe* Defendants' VCDs still have some value" theory that is based on unsound methodologies, and ignores the basic factual and regulatory features that shape and provide guardrails for the available decisions of consumers. And now, Defendants' Opposition essentially concedes that Dr. Keller's analysis only works, *maybe*, if one poses the question both retrospectively and in a highly factually misleading manner. For all the discussion about consumer behavior, Dr. Keller simply ignores the decisions and actions of consumers both before and after they learned of NDMA/NDEA in Defendants' VCDs, and never conducted a proper consumer behavior analysis (conjoint analysis) that she has conducted in past matters. The result is not a surprise: No consumer would ever choose the cancer option when *the exact same* non-cancer option is and was available to them at all material times.

Finally, Dr. Keller is simply unqualified to critique Dr. Conti's damages analysis, which is firmly rooted in classical economic theory concepts, and Dr. Keller's attempt to graft her own behavioral science ideas onto Dr. Conti's report is simply proof of her lack of adequate qualifications to engage with it.

II. ARGUMENT

A. Dr. Keller's Methodology Is Unsound Because Her Report's Citations Do Not Support Her Conclusions

Defendants argue that Dr. Keller's opinions find support in no less than 48 published sources, including literature and empirical studies. (Opp'n, at 7-8.) This is not true. All of Dr. Keller's cited studies discuss in general terms how consumers place different weights on *multiple various features* when it comes to medications.

Dr. Keller could not conjure a single citation to support her "maybe, probably, likely" hypothesis that *all other things being equal*, any rational consumer would choose the carcinogen-laced option. The leap Dr. Keller would ask the jury to take from her sources to her opinions is fundamentally unsound.

Dr. Keller's examples elucidate just how off point and unreliable she is. Defendants continue to discuss Dr. Keller's Accutane example as if Plaintiffs' only issue was the fact that Accutane's risks were disclosed, while NDMA/NDEA in Defendants' VCDs was not disclosed (as Defendants concede). Although that difference alone makes it a seriously inappropriate analogy to the facts of this case, it is not the only reason why the example is improper. Rather, consumers have a plethora of treatment options for their acne, of which Accutane is just one,[1] and its consideration as an option would occur *prior* to any decision having been made. Here, Plaintiffs and Class Members all previously engaged in that very product feature weighing for their hypertension management, and already made a choice to take generic versions of DIOVAN® and/or EXFORGE® as evidenced by their product purchases resulting in their class membership. These were not zombies sleep walking to the pharmacy to fill their prescriptions, as Dr. Keller conceded. (Keller Dep. 159:23-160:13 (Pls' Mot., Ex. 2).) At the time of purchase, the weighing of the various features had already taken place and every single Plaintiff and Class Member had chosen FDA-approved valsartan therapeutically equivalent to the brand, as this Court has recognized previously. (Dkt. No. 775, at 14, 20.)

[1] Notably, per its label, Accutane is only to be prescribed to patients who have failed other forms of "conventional therapy" for acne treatment (i.e., as a last resort option). In addition, it may only be prescribed pursuant to other restrictive REMS criteria as set forth in the label. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/18662s051lbl.pdf (last visited June 16, 2022).

The more appropriate Accutane-related analogy would have been to study the responses of patients who received Ranbaxy's adulterated branded-generic version of Accutane in 2005-2006 (for which Ranbaxy would later enter a civil and criminal settlement with DOJ), to see whether those consumers would have preferred the non-adulterated version. Dr. Keller's response at her deposition was speculative and cynical, non-responsive, and exemplified her failure to understand the guardrails that shape consumers' real life decisions. She *speculated* cynically that "there are consumers out there who believe that pure drugs is an oxymoron[.]"[2] (Keller Dep. 153:16-18.) And then she displayed her lack of understanding regarding generic drugs:

> **Q.** Well, what if -- I mean, we're talking about just one manufacturer's version of generic Accutane, you wouldn't want to know that so you could just take another manufacturer's version of generic Accutane that wasn't adulterated?
> **A.** It's a hypothetical, so I'm giving you a hypothetical back, and that is, if I like this one that I'm taking and it's worked for me -- and back to my framework that I talk about in the model, and I'll use MICI this time, which is, depending on the message that I got -- and I can give you examples, depending on -- I'm focusing on the individual differences, that if I've tried other acne medicines and they haven't worked for me, and then I find one that I really like and it seems to work for me, and then there is this information out there, I'm saying that there are some consumers in those situations that might not want to know or not care about this information about the adulteration from this specific batch because they don't want to switch, they don't want to consider any alternative products.
> **Q.** Do you understand that the point of our generic drug system is that all the generics are supposed to work in the same way to each other and to the brand?
> MR. GOLDBERG: Objection.
> BY MR. DAVIS:
> **Q.** Do you understand that?
> MR. GOLDBERG: Objection to form. Asked and answered.
> **A. I am not an expert on how generics are supposed to work, and I will not give you an opinion on that.**

(Keller Dep. 155:22-157:10 (Pls' Mot., Ex 2 (emphasis added)).)

[2] There will be many more of these types of people out there if Defendants are allowed to evade liability in this litigation.

Ultimately, the absence of such a study for Dr. Keller to cite itself is telling; no researcher would ever bother to study the question because it is beyond serious scientific debate. Dr. Keller's cynicism, speculative say so, and false equivalencies do not amount to a reliable methodology to support an otherwise specious opinion: that consumers would prefer the cancer option (Defendants' VCDs) when ***the exact same thing*** is available to them in a non-cancer option (non-defendant VCDs that were available and on the market). And her admission of lack of knowledge about generic medications likely contributes to her unreliable approach.

This is exactly the type of "subjective belief or unsupported speculation" opinion the Third Circuit admonishes district courts to exclude.[3] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994).

B. <u>Dr. Keller's "Feeling" That a Study Was Not Necessary Is Not Reliable and She Is Not Qualified to Interpret FDA Regulatory Actions</u>

Plaintiffs argued in the Motion that Dr. Keller broke her own rule that she had stated to another court that "empirical testing is always required[.]" (Pls.' Mot., at 9-10.) Defendants argue in opposition that Dr. Keller did not do her own study because of her "feeling" that there was enough evidence to support her opinions. (Opp'n, at 13-14.)

As pointed out above, Dr. Keller has <u>*zero*</u> evidence to support her far out opinion that any sound-of-mind consumer would prefer the cancer option versus *the exact same* non-cancer option,

[3] Dr. Keller and Defendants in their Opposition assert without citation that a single serving of bacon contains NDMA levels 50% higher than the FDA's acceptable limits ("AIs") for VCDs. Dr. Keller is obviously unqualified to opine on NDMA levels in bacon and health risks associated therewith. Regardless, the false equivalency is the same as it is with Accutane, namely, Dr. Keller's failure to recognize that the *exact same thing* was available minus the cancer agents (*i.e.*, other non-adulterated valsartan products on the market at all times). Even so, and taking Dr. Keller's citation at face value, ingesting ZHP's VCDs, for example, would be like ingesting hundreds of servings of bacon *every day*. No consumer of Defendants' VCDs ever voluntarily made that choice with knowledge.

and her 48 citations do not lend any support whatsoever. As Defendants' own legal citations set forth, there is simply "'too great an analytical gap between'" Dr. Keller's citations and her opinion proffered. (Opp'n, at 14 (citing and quoting *Rhoads Indus. v. Shoreline Found., Inc.*, No. 15-921, 2021 U.S. Dist. LEXIS 124066, at *22 (E.D. Pa. July 2, 2021)).)

Instead of empirical testing, Defendants argue that Dr. Keller's amassed real world observational evidence is enough, despite her lack of knowledge regarding generic prescription drugs. That evidence is culled either from out of context selective quotes from class representatives under defense attorney cross examination (where Defendants themselves admit all of these class representatives also testified they would not have purchased Defendants' VCDs had they known of the NDMA/NDEA, *see* Opp'n, at 17) or based on Dr. Keller's improbable interpretations of FDA regulatory actions regarding setting AIs for VCDs. The former are admittedly not reliable as Dr. Keller conceded both in her report and deposition; the latter Dr. Keller is simply not qualified to opine on. Dr. Keller displayed such a lack of understanding of prescription drug regulations that interpreting toxicology-based AIs is well beyond her expertise. Among other things, Dr. Keller testified:

- She had no understanding of whether NDMA/NDEA were supposed to be in Defendants' VCDs or not (Keller Dep. 177:16-179:12);
- She was not familiar with the prescription drug approval process in the United States (Keller Dep. 29:22-30:3 (**Ex. 1**[4]));
- She had no understanding of how generic drugs get approved in the US (Keller Dep. 68:21-24 (**Ex. 1**));
- She had no understanding that generic drugs were supposed to be therapeutically equivalent to each other and to the brand (Keller Dep. 156:23-157:10);
- She did not know what an FDA-approved label was (Keller Dep. 73:14-16);
- She did not know what an NDA or an ANDA was (Keller Dep. 30:18-22 (**Ex. 1**));
- She did not look at "any FDA regulations of general applicability to prescription pharmaceuticals" (Keller Dep. 35:13-17 (**Ex. 1**));

[4] Other citations to Dr. Keller's deposition testimony refer back to the excerpts filed as part of Plaintiffs' opening Motion, at Exhibit 2.

- She did not understand the meaning of the terms "adulteration" or "misbranding" or the prohibition under federal law of selling adulterated drugs (Keller Dep. 36:12-17 (**Ex. 1**), 173:23-174:2);
- She did not understand what happens to recalled pharmaceuticals once recall is announced (Keller Dep. 168:14-21 (**Ex. 1**)); and,
- She had only studied chemistry in high school and had no working knowledge of toxicology (Keller Dep. 36:22-37:6 (**Ex. 1**)).

Given these answers, it is implausible that Dr. Keller can be tasked with reliably interpreting for the jury or factfinder the significance of the FDA's setting of NDMA/NDEA AIs pursuant to ICH M7 for VCDs when she did not understand, among other things, whether NDMA/NDEA were supposed to be in VCDs or not. She is simply not qualified, and any opinion she provided is clearly a net opinion corrupted by her lack of foundational knowledge.

C. Dr. Keller and Defendants Cite Nothing to Support Their Position that Damages Should Be Evaluated Based on Subjective and Retrospective Interviews with Class Members

Just like Dr. Keller, Defendants appear to concede that Plaintiffs and Class Members were not able to consider the NDMA/NDEA contamination at the time of purchase of Defendants' VCDs. No matter, Defendants posit, because damages should be measured retrospectively based on subjective interviews with each Plaintiff and Class Member. (Opp'n, at 12-13.)

The problem is that Dr. Keller and Defendants provide *zero* citation to how this is an appropriate way to measure damages, much less any citation that this is the *only* viable way to measure economic damage:

> **Q.** What literature do you have to support what appears to be your proposition that an economic damages analysis should be based on a retrospective look as opposed to measuring at the time of injury?
> **A.** I am not a lawyer. I don't have an opinion on that.

(Keller Dep. 190:14-20 (**Ex. 1**).) It is not surprising that Dr. Keller would not be able to provide any such citation, nor even understand that it is her obligation – not her lawyers' – to provide

citations for her propositions to be reliable, because she has "never done an economic damages analysis" in litigation or otherwise, and is not an economist. (Keller Dep. 230:5-15 (**Ex. 1**).)

It has been well established for over 100 years that in any lawsuit for damages, loss must flow out of the injury and be its natural and proximate consequence. *Smith v. Bolles*, 132 U.S. 125, 130 (1889); *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 34-36 (2013). In this case, Plaintiffs' economic injury was Plaintiffs' purchase of Defendants' adulterated VCDs that breached warranties, and based on Defendants' false representations. Dr. Conti's economic damages model adheres to this guidance; Dr. Keller's rough sketch of an idea for retrospective interviews where class members are presented with misleading questions does not.

D. <u>Dr. Keller's Critique of Dr. Conti's Report Falls Flat</u>

Dr. Keller is admittedly not an economist, and Defendants' efforts to cast her as qualified based on her dealings with behavioral economics does not qualify her to opine on matters of classical economics as applied by Dr. Conti. The best proof of this is Dr. Keller's inability to grapple with Dr. Conti's concepts *per se*, instead attempting to transmogrify them into her own behavioral science discipline (e.g., asserting that Dr. Conti is applying a "uniform non-compensatory decision rule" but admitting that Dr. Conti never used those words (Keller Dep. 125:3-126:6)).

Dr. Keller simply did not understand *why* Dr. Conti removed the supply curve, which was not based on any decision rule applied by consumers, but rather because there was *no lawful supply*. Dr. Keller of course would not have understood this, because she was unaware of the basic facts and background including whether NMDA/NDEA were even supposed to be in Defendants' VCDs, the meaning or implications of the FDA's findings of Defendants' VCDs to have been adulterated pursuant to federal law, or what the effect of a recall is.

Defendants argue that "Dr. Keller has offered no opinions regarding when a drug may or may not lawfully be sold." (Opp'n, at 21.) This is not accurate. Dr. Keller explicitly takes issue with Dr. Conti's removal of the supply curve. (Keller Report ¶¶ 66, 71 (Dr. Keller stating "instead of simply making the supply curve of at-issue VCDs disappear, Dr. Conti should have examined the change in demand….")).) Dr. Keller then puts forward her own supply-demand model, which she admitted at her deposition included a "hypothetical" supply line. (Keller Report ¶ 71; Keller Dep. 186:6-189:1.)

Either Defendants are retracting Dr. Keller's opinions for her, or she was simply too uninformed to offer them in the first place. She admitted she never "looked into how the fact of adulteration might affect the supply of a drug in the US." (Keller Dep. 171:5-21 ("I have no opinion on drug supply….").) Either way, she should not be permitted to present her unreliable opinions to a jury or factfinder.

Putting aside whether the opinion was offered or not or is now retracted as Defendants claim, Dr. Keller undercut herself even further by actually agreeing with Dr. Conti's conclusion that the supply curve should be removed. Dr. Keller agreed "[t]here would be no intersection of supply and demand" and consumers "would end up [] paying no money" for Defendants' at-issue VCDs after they were removed from the lawful market. (Keller Dep. 197:22-198:19.) And Defendants themselves own up to the predicate facts in their Opposition. (Opp'n, at 21 (admitting that, for example, "ZHP products could not be sold in the United States after the recall").)

Dr. Keller's critique of Dr. Conti is retracted, without adequate qualification, and is ultimately baseless as evidenced by Dr. Keller's ultimate capitulation that Dr. Conti got it right.

III. CONCLUSION

For the foregoing reasons, Dr. Keller should be excluded from offering her opinions related to class certification.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2022, a true and correct redacted copy of the foregoing was filed and served via the Court's CM/ECF system, and an undredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch
David J. Stanoch